



**Billing Code 4910-9X**

**DEPARTMENT OF TRANSPORTATION**

**Office of the Secretary**

**49 CFR Part 40**

**[Docket No. OST-2015-0045]**

**RIN 2105-AE35**

**Use of Electronic Chain of Custody and Control Form in DOT-Regulated Drug Testing Programs**

**AGENCY:** Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** This action amends the U.S. Department of Transportation's (DOT) regulations to incorporate changes to the Substance Abuse and Mental Health Services Administration's (SAMHSA) chain of custody and control form (CCF) recently approved by the Office of Management and Budget (OMB). Specifically, this rulemaking expands the DOT's definition of the CCF to include both paper and electronic forms.

**DATES:** This final rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** For technical questions about this action,

contact Mark Snider, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Ave. SE; Washington, DC 20590; telephone: (202) 366-3784; email: ODAPCWebMail@dot.gov.

## **SUPPLEMENTARY INFORMATION:**

### **Good Cause for Immediate Adoption**

Section 553(b)(3)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” In this instance, the DOT finds that notice and public comment to this immediately adopted final rule, as well as any delay in the effective date of this rule, is unnecessary, given that the electronic CCF (eCCF) has been approved for use by OMB and the DOT is bound by statute to follow SAMHSA’s chain of custody and control procedures, to include use of an OMB-approved CCF.

#### **I. Authority for this Rulemaking**

This rulemaking is promulgated pursuant to the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102-143, 105 Stat. 952, (Oct. 28, 1991)).

#### **II. Background**

The Federal Workplace Drug Testing Program was established by Executive Order 12564 on September 15, 1986, and further mandated by Congress in section 503 of Public Law 100-71 (July 11, 1987). The Department of Health and Human Services (HHS), in developing the program, created a comprehensive set of standards for the Federal workplace drug testing program, including chain of custody procedures designed to ensure the integrity and security of specimens from the time the specimen is collected until the time the testing results are reported

by the laboratory. To satisfy the congressional mandate, HHS first issued its mandatory guidelines on April 11, 1988, and in doing so, created the uniform CCF. The CCF is the tool by which agencies and participants in the testing process are assured that the specimen collected is actually that of the tested employee. At this time, DOT developed its controlled substance program, following in large part the mandatory guidelines set forth by HHS.

On October 28, 1991, Congress passed OTETA, which codified the DOT's controlled substance testing program for its regulated entities and added a requirement to develop an alcohol testing program. In codifying the DOT program, Congress directed the Department to continue to "incorporate the [HHS] scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing ... strict procedures governing the chain of custody of specimens collected for controlled substances testing." See Pub. L. 102-143. As a result of this mandate, the DOT has required its regulated entities to use the CCF, as developed by HHS and approved by OMB. Historically, the CCF only has been available for use in paper form. On May 28, 2014, OMB approved the use of both a paper form CCF and an eCCF under the HHS Mandatory Guidelines. This final rule is necessary to expand the DOT's definition of the CCF to include the OMB-approved eCCF.

As noted above, the CCF is used to identify a specimen and to document its handling at the collection site. The paper CCF is a carbonless form consisting of 5 copies as follows:

Copy 1	Test Facility Copy
Copy 2	Medical Review Officer Copy
Copy 3	Collector Copy
Copy 4	Employer Copy
Copy 5	Donor Copy

The eCCF requires the same collection of information and distribution of information to the

relevant parties as the paper CCF requires. With the approved eCCF, HHS is not requiring collection of any new or different information. The only change from the paper CCF to the eCCF is the mechanism for collecting and transmitting the requisite information. Before implementing an eCCF, HHS-certified laboratories must provide a detailed plan and proposed standard operating procedures (SOPs) for SAMHSA to review and approve through SAMHSA's National Laboratory Certification Program (NLCP). The review of validation records, specimen records, SOPs, staff training records, and practices associated with the eCCF will be part of the NLCP inspection process. Once the eCCF is approved for use through the NLCP inspection process, it may be used in the DOT drug testing program, as well as the Federal Workplace Drug Testing Program. For more information regarding this approval process, please contact the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, National Laboratory Certification Program at (919) 541-7242, or via email at [nlcp@rti.org](mailto:nlcp@rti.org).

It is important to note that electronic signatures are not otherwise acceptable in Part 40. The use of the eCCF will create an exception so that electronic signatures will be acceptable on these forms only and not throughout the rest of Part 40.

To ensure that the DOT regulations conform to SAMHSA's approved chain of custody and control procedures, the DOT is issuing this final rule to expand the current definition of the CCF in 49 CFR 40.3 to include all versions of the CCF as approved by OMB. We are amending § 40.45 to explain that the 5-part form can be a paper form or an approved electronic form, as long as the employer ensures that security and confidentiality concerns are addressed. The DOT is amending § 40.73 to require entities using an eCCF to follow the eCCF procedures approved

by SAMHSA through the NLCP inspection process.

### **III. Regulatory Analyses and Notices**

Changes to Federal regulations must undergo several analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Public Law 96-354), as codified in 5 U.S.C. 601 *et seq.*, requires agencies to analyze the economic impact of regulatory changes on small entities. The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Finally, section (a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108-447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107-347, 116 Stat. 2889 (Dec. 17, 2002) requires DOT to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. This portion of the preamble summarizes the DOT's analyses of these impacts with respect to this final rule.

#### **Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures**

This final rule is not a significant regulatory action under Executive Order 12866 and 13563, as well as the Department's Regulatory Policies and Procedures. Its provisions make conforming amendments to include forms that have already been approved for use by OMB and

that, by statute, the DOT is required to use. This rule does not propose any major policy changes or impose significant new costs or burdens. Rather, this rule is expected to reduce paperwork burdens for those entities that elect to use the new eCCF, as noted in SAMHSA's information collection request for the CCF that was approved by OMB. For more information, you may review SAMHSA's information collection request (ICR) 201307-0930-003 and supplemental information at [www.reginfo.gov](http://www.reginfo.gov).

#### Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Public Law 96-354, "RFA"), 5 U.S.C. § 601 *et seq.*, establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify, and a regulatory flexibility analysis will not be required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule does not require entities to use an eCCF. Rather, it presents another means of compliance for all entities, as is currently permitted under the HHS mandatory guidelines. It does not create additional burdens, but may alleviate some paperwork burdens if entities opt to use the eCCF. Thus, in accordance with 5 U.S.C. 605(b), I certify that this rule will not have a significant economic impact on a substantial number of small entities.

#### Paperwork Reduction Act

The PRA requires that the DOT consider the impact of paperwork and other information collection burdens imposed on the public. Because the DOT is obligated by statute to use whatever procedures and forms that SAMHSA adopts with respect to chain of custody and control for drug testing specimens, SAMHSA has accounted for the DOT burden in its recently approved information collection request. For more information regarding these burdens, you may review SAMHSA's ICR 201307-0930-003 and supplemental information at [www.reginfo.gov](http://www.reginfo.gov).

#### Privacy Act

The DOT conducted a PIA of this rule as required by section 522(a)(5) of division H of the FY 2005 Omnibus Appropriations Act, Public Law 108-447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107-347, 116 Stat. 2889 (Dec. 17, 2002). The assessment considers any impacts of the final rule on the privacy of information in an identifiable form. In addition to the PIA issued by HHS in conjunction with its ICR for the approved CCF, the DOT issued a supplemental PIA, further explaining how the eCCF may be used by DOT-regulated entities and the measures that have been put into place to ensure not only the integrity and security of the testing process, but the privacy of individuals subject to testing.

Copies of the DOT's supplemental PIA, as well as SAMHSA's PIA, have been placed in the docket for this rulemaking.

## **V. How To Obtain Additional Information**

### **A. Rulemaking Documents**

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal Document Management System (FDMS) Portal

(<http://www.regulations.gov>); or

2. Access the Government Printing Office's Web page: [www.gpo.gov](http://www.gpo.gov).

### **List of Subjects in 49 CFR Part 40**

Administrative practice and procedure, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation

## **The Amendment**

In consideration of the foregoing, the Department of Transportation amends part 40 of Title 49, Code of Federal Regulations, as follows:

### **PART 40-PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS**

1. The authority citation for part 40 continues to read as follows:

Authority: 49 U.S.C. 101, 102, 301, 322, 5331, 20140, 31306, and 45101 et. seq.

2. In § 40.3 revise the definition of “chain of custody” to read as follows:

#### **§ 40.3 What do the terms of this part mean?**



\* \* \* \* \*

*Chain of custody.* The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF) as approved by the Office of Management and Budget.

\* \* \* \* \*

3. Amend § 40.45 by revising paragraph (a) and adding paragraphs (c)(5) and (f) to read as follows:

**§ 40.45 What form is used to document a DOT urine collection?**

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. You may view this form on the Department's web site (<http://www.dot.gov/odapc>) or the HHS web site (<http://www.workplace.samhsa.gov>).

\* \* \* \* \*

(c) \* \* \*

(5) When using an electronic CCF, you must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic form.

\* \* \* \* \*

(f) An employer who uses an electronic CCF must ensure that the collection site, the primary and split laboratories, and MRO have compatible systems, and that the employee and any other program participants in the testing process will receive a legible copy of the CCF.

4. Amend § 40.73 by revising paragraph (a) introductory text, redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b) to read as follows:

**§ 40.73 How is the collection process completed?**

(a) As the collector, when using the paper CCF, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (7) of this section in the employee's presence.

\* \* \* \* \*

(b) As a collector, when using other forms of the CCF as approved by the Office of Management and Budget, you must follow the procedures approved for that form.

(c) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case, within 24 hours or during the next business day.

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Issued under the authority provided in Pub. L. 102-143, in Washington, DC, on April 6, 2015.

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Anthony R. Foxx

Secretary of Transportation

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